

Information for HSR&D's December 15, 2005 proposal submission date

Updated 10/24/05

DEADLINES: November 2, 2005—Intent to Submit due in VACO

November 2, 2005—Abstract due in VACO

December 15, 2005—Proposals due in VACO

Please note: The Intent to Submit and Abstract must be submitted by the designated deadline in order for a proposal to be submitted. Proposals that have not complied with this requirement will not be accepted for review.

IMPORTANT CHANGES:

<u>Proposal Submissions</u>: Due to use of the "Just in Time" submission option, several documents, previously required as part of the proposal submission package, can be submitted after a proposal is approved for funding. Use the **REVISED CHECKLIST** to prepare your proposal and "Just in Time" submission packages.

<u>Funding Priorities</u>: In order to encourage investigators to conduct research in areas of high interest to HSR&D, proposals that respond to targeted solicitations will be given special consideration. The merit review score, which is based on significance, approach, innovation, and environment, will continue to serve as the main determinant for identifying proposals that will be considered for funding. Proposals with fundable scores that are also responsive to targeted solicitation requests will be given priority funding consideration. For additional information refer to "HSR&D Priorities for Investigator Initiated Research-FY 2006" which can be downloaded from the HSR&D website: www.hsrd.research.va.gov.

<u>Budget Limits</u>: Note that HSR&D reviews individual project budgets very carefully before negotiating final funding decisions. Moreover, proposals that exceed \$300,000 in any one year or a total of \$900,000 (including all salary costs) are no longer being accepted for review by HSR&D.

<u>Clinical Trial Registration</u>. Proposals that are clinical trials must be registered prior to enrollment of subjects or allocation of funding. The VA Office of Research and Development (ORD) defines a clinical trial as any research that prospectively assigns human subjects or groups of subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome. The Principal Investigator, who is responsible for ensuring that the project is properly registered, must contact the HSR&D representative at <u>ART@med.va.gov</u> with project specific details. For further information regarding the registration process and required information please refer to: http://www.va.gov/resdev/resources/ORD_Admin/clinical_trials/default.cfm.

INTENT TO SUBMIT (ITS) INSTRUCTIONS:

- 1) Download and open the ITS Spreadsheet (Note: the first row, shaded in yellow, is an EXAMPLE)
- 2) Edit the spreadsheet by entering the information for each proposal your site plans to submit to HSR&D (you should have one row for each proposal). **HINT:** When entering data in the Excel spreadsheet, use Alt-ENTER, to force a new line within a cell. Please contact Noahline Stuart at 202-254-254-0224 if you have any questions about the Excel spreadsheet.
- 3) If there is a field you cannot complete or that does not apply, leave it blank

- 4) <u>Clinical Trial</u>: For each proposal that involves clinical trials research, that is, any research that prospectively assigns human subjects or groups of subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome, type "YES" in the "Clinical Trials" column on the Intent to Submit spreadsheet.
- 5) <u>Combined Data Monitoring Board</u>: For each proposal that is a multi-site, randomized control trial (randomized by patient or by provider and include patients) with <u>more than one Institutional Review Board</u>, type "YES" in the "Combined Monitoring Board" column on the Intent to Submit spreadsheet.
- 6) **Review Group**: For each proposal, the Principal Investigator must suggest the review group which would be most appropriate for the proposal. For guidance as to the focus of proposals that are reviewed by each group, see the attached document entitled "**Review Group Topics**". Note that HSR&D staff will make the final decision regarding review group assignment. Service Directed Projects for Implementation should be clearly designated (use SDP in the review group field) and will undergo a special review process separate from Investigator Initiated Research projects.
- 7) <u>Responsive to a targeted solicitation</u>: Identify the targeted solicitation to which the proposal is responding if the Principal Investigator plans to provide a rationale for identifying the proposal as responsive to a targeted solicitation.
- 6) **Save** the spreadsheet with your changes.
- 7) Prepare an e-mail to convey the ITS spreadsheet to VACO

To e-mail the Intent to Submit spreadsheet from within the VA system:

click on a "new mail message" in Outlook, and in the "TO:" line type "VHA CO HSR&D ITS". In the subject line state the facility name, station number, and last name of the Principal Investigator(s) who are submitting ITS information (for example: Durham, NC 508: Jones, Smith). Attach the spreadsheet and send.

To e-mail the Information to Submit spreadsheet from outside the VA system:

the correct e-mail address is whacohsr&dits.vhacohsr&dits@va.gov. In the subject line state the facility name, station number, and last name of the Principal Investigator(s) who are submitting ITS information (for example: Durham, NC 508: Jones, Smith). Attach the spreadsheet and send.

If you encounter any problems, contact Rita Lysik at 202-254-0212.

ABSTRACT SUBMISSION INSTRUCTIONS:

To facilitate assignment of a proposal to a portfolio area for review, and the selection of appropriate reviewers, please e-mail a copy of the proposal abstract to VACO.

To e-mail the project abstract from within the VA system:

Click on a "new mail message" in Outlook, in the "TO:" line type "VHA CO HSR&D Abstracts" (this is the name for the mail box in the global address book in the Outlook application). In the subject line state the facility name, station number, and last name of the Principal Investigator(s) who are submitting abstracts (for example: Durham, NC 508: Jones, Smith). Attach the abstract(s), and send.

To e-mail an abstract from outside the VA system:

If you encounter any problems, contact Rita Lysik at 202-254-0212.

Please ensure that the abstract page of the Merit Review Proposal forms follows the format specified below:

Title of Proposal:

Proposal Number (if Resubmission):

Principal Investigator:

VAMC:

Responsive to Solicitation: (Indicate Title of Solicitation/Date/Targeted Area)

A. PROJECT DESCRIPTION

Background/Rationale: Why is this study important? Why is it relevant to VA? **Objective(s)**: Major goal(s), specific research question(s) and objective(s).

Methods: Study design (e.g., randomized controlled trial, cohort study, case-control, etc.).

Major characteristics (e.g., age, gender, diagnosis, inclusion/exclusion criteria) and size of the sample, and any control group; the intervention; and the setting. Indicate if non-VA sites are

included.

Major variables and source(s) of data.

Main types of analysis (decision modeling, cost-effectiveness, qualitative techniques, meta-

analysis, etc.).

B. IMPACT

Impact Statement: What is the nature of the impact (anticipated) on veterans, the VA health care system, and the general public (e.g., improved quality of care, better patient outcomes, lower cost, better management, increased patient satisfaction, etc.)?

Consider clinical, research, and policy applications. What steps have been taken to increase the impact of the research?

PROPOSAL SUBMISSION INSTRUCTIONS:

Carefully follow instructions for proposal submission as specified in HSRD's Handbook 1204.1. This document can be downloaded from HSR&D's web site at www.hsrd.research.va.gov. Place the original copy of the proposal a folder. Label the front of the folder with the Principal Investigator's name and the Proposal Title. Social Security numbers should be included ONLY on the original 1313-1. Proposals that do not redact Social Security information from copies will be returned to the station and not reviewed.

PROPOSAL SUBMISSION INSTRUCTIONS (Resubmissions only):

Each proposal that is being resubmitted for review must include a copy of the notification letter, summary statement, and critiques of any prior review of the proposal, as well as the most recent letter of intent and response (*if applicable*). This information must be included after the proposal narrative and any appendices. If you have any questions about this requirement, please contact Rita Lysik, 202-254-0251 or rita.lysik@va.gov.

Help:

Scientific questions, including to which review group the proposal should be assigned, may be addressed to the following individual:

Equity: Rachael Evans, MPA at 202-254-0133 or rachael.evans@va.gov

Women's Health: Linda Lipson, MA at 202-254-0231 or linda.lipson@va.gov

Special Populations: Martha Bryan, EdD at 202-254-0251 or martha, bryan@ya,gov

Rehabilitation Outcomes: Martha Bryan, EdD at 202-254-0251 or martha.bryan@va.gov

Implementation and Management Research: Caryn Cohen, MS at 202-254-0218 or caryn.cohen@va.gov

Quality Measurement and Effectiveness: Pauline Sieverding, PhD, JD, MPA at 202-254-0249 or

Chronic Disease Management: Pauline Sieverding, PhD, JD, MPA at 202-254-0249 or

Long Term Care & Aging: Pauline Sieverding, PhD, JD, MPA at 202-254-0249 or

Research Methodology: Phil Crewson, PhD at 202-254-0220 or phil.crewson@va.gov

Nursing Research Initiative (ORD-wide): Susan Schiffner, RN, BSM, CCM at 202-254-0209 or susan.schiffner@va.gov

General administrative questions or questions about proposal submission instructions can be addressed to Rita Lysik, 202-254-0212 or rita.lysik@va.gov

Helpful Hints: (to make proposal processing easier for CO staff)

- Please choose a box that the proposals fit in snuggly. If there is extra space the boxes do not survive shipping well. Boxes used to ship copy paper can be recycled effectively for this purpose. Fill any unoccupied space with filler.
- Please do not use "popcorn" or shredded paper as filler since it creates a mess. We suggest that
 you use bubble wrap or wadded up paper.